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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/636,206	04/22/96	LUKIC	G
			EXAMINER

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13M1/0506

ART UNIT	PAPER NUMBER
1301	5

DATE MAILED: 05/06/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 15-22 is/are pending in the application.
- ☐ Of the above, claim(s) 18 and 19 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 15-17 and 20-22 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☒ received in Application No. (Series Code/Serial Number) 08/173542
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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1) This application contains claims directed to the following patentably distinct species of the claimed invention:

species #1 - method for covering a stent including adhering the stent to a tube using chemical bonding or using curable adhesive or using elastomeric composition dissolved in solvent.

species #2 - method for covering a stent including removing stent from tube/surface.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant

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must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2) During a telephone conversation with Philip Strassburger on 3-14-97 a provisional election was made without traverse to prosecute the invention of species # 1, claims 15-17 and 20-22. Affirmation of this election must be made by applicant in responding to this Office action. Claims 18 and 19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3) The disclosure is objected to because of the following informalities: The insertion before the first line filed 4-22-96 (paper #2) incorrectly identifies application 08/346,066 as being a "continuation" of application 08/173,542 because application 08/346,066 is a "division" of application 08/173,542.

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Appropriate correction is required.

4) Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, the recitation of "curing the adhesive medium between at least the portion of the stent in the tube" (emphasis added) is awkward / ambiguous.

In claim 17, the recitation of "polymerizing the elastomeric composition to the tube and to the stent" (emphasis added) is awkward / ambiguous.

5) 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

6) Claims 21 and 22 are rejected under 35 U.S.C. 101 because they appear to have the same scope.

A difference in scope is not caused by the use of the curable "adhesive medium" in claim 21 and the use of the "polymerisable composition" in claim 22.

7) Claims 15-17 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The step of "radially expanding at least the portion of the stent in the tube or allowing at least the portion of the stent to expand in the tube" (emphasis added) as set forth in claims 15-17 and 20-22 is not reasonably conveyed by the original specification (is new matter) since the original specification only supports allowing the stent to radially expand.

8) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9) Claims 15-17 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacGregor (US Patent 5,015,253) in view of Gianturco (US Patent 5,282,824) and Kaster (US Patent 4,444,215) and optionally further in view of Simon et al (US Patent 5,384,308).

MacGregor teaches that in one method of deploying, stents are compressed circumferentially so that it may be fitted within

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a tubular body, such as a catheter and subsequently the stent is expanded (column 1 line 65-column 2 line 50). MacGregor teaches applying or bonding an appropriate coating directly to the exterior surface of the stent 21 (column 5 lines 51-60). MacGregor does not specifically recite covering the stent with a preformed tubular cover.

As to claims 15-17 and 20-22, it would have been obvious to one of ordinary skill in the art to position the stent 21 of MacGregor within a preformed cover and to bond the preformed cover to the stent since:

(A) MacGregor suggests applying or bonding a coating (covering) to the stent;

(B) Gianturco suggests covering a stent with a preformed sleeve; and

(C) Gianturco and Kaster suggest bonding covering material to a stent.

The limitation of the material of the covering being elastomeric (claims 15-17) or polymer (claims 20-22) would have been obvious to one of ordinary skill in the art since it is conventional to make covering material for a stent out of elastic / polymer material as evidenced by Gianturco (abstract), Kaster (column 6 lines 25-44, column 7 lines 12-25) and optionally Simon

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et al (column 4 lines 27-47); it being noted that Simon et al is also further evidence of a suggestion to use a preformed cover for a stent.

As to the technique used to assemble the stent and the preformed tube as set forth in claims 15-17 and 20-22, it would have been obvious to one of ordinary skill in the art to compress the stent, insert the stent into the preformed cover and expand the stent within the preformed cover so as to position the stent within the preformed cover since MacGregor suggests facilitating assembly of the stent within another tube by compressing the stent and inserting the compressed stent into the another tube.

As to the type of bonding in claims 15 and 20, it would have been obvious to one of ordinary skill in the art to bond using "chemical bonding" in view of the above noted suggestion from Gianturco and Kaster to bond covering material to a stent.

As to the type of bonding in claims 16 and 21, it would have been obvious to one of ordinary skill in the art to bond using a "curable adhesive medium" in view of (a) the above noted suggestion from Gianturco and Kaster to bond covering material to a stent, (b) it is taken as well known / conventional in the bonding art to bond a first tubular member to another tubular member by coating the inside of the first tubular member with

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adhesive and then to insert the second tubular member into the first tubular member and (c) "curable adhesive medium", which is cured to effect bonding, is taken as a well known / conventional type of adhesive in the bonding art.

As to the type of bonding in claims 17 and 22, it would have been obvious to one of ordinary skill in the art to bond using "elastomeric composition dissolved in solvent" in view of (a) the above noted suggestion from Gianturco and Kaster to bond covering material to a stent, (b) it is taken as well known / conventional in the bonding art to bond a first tubular member to another tubular member by coating the inside of the first tubular member with adhesive and then to insert the second tubular member into the first tubular member and (c) "elastomeric composition dissolved in solvent", which is has the solvent evaporized and the elastomer composition polymerized is taken as a well known / conventional type of adhesive in the bonding art.

10)

## REMARKS

Scott et al (abstract / figure 3), Cragg (column 3 lines 13-33), Kwan-Gett (figure 7), German 3918736 (translation), Matsuno et al (figures 1, 2), Palmaz (figures 5, 6), Palmaz et al (figures 10A, 10B) are cited of interest for showing a covered stent.



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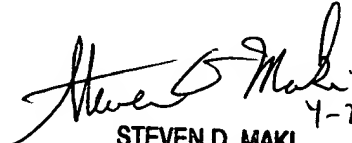
Susawa et al is cited of interest for figure 2.

The references crossed off the PTO 1449 are not readily available to the examiner.

11) No claim is allowed.

12) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven D. Maki whose telephone number is (703) 308-2068. The examiner can normally be reached on Monday to Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Ball, can be reached on (703) 308-2058. The fax phone number for Art Unit 1301 is (703) 305-7115. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0651.

Steven D. Maki  
April 28, 1997

  
4-28-97  
STEVEN D. MAKI  
PRIMARY EXAMINER  
GROUP 1300